

### **REMARKS**

Claims 1-4, 6-9, 11-16, 30 and 31 are pending. No new matter has been added by way of the present submission. For instance, the language claims 1, 9, 11, 12, 14, 15 and 16 has been amended to clarify the nature of the present invention. Additionally, claims 1, 9, and 14 have been amended in order to reference the minimum promoter as comprising the nucleotide sequence of SEQ ID NO: 5. Additionally, claims 1, 11, 12 and 14 have been amended to indicated that the ligand-responsive transcription control factor is one selected from an aryl hydrocarbon receptor, estrogen receptor, androgen receptor or thyroid hormone receptor as supported by originally filed claims 4, 6, 7 and 8. Lastly, the dependencies of several claims has been slightly modified, for instance, references made to change the dependencies in claims 11, 12 and 13. Additionally, newly added claim 30 further defines the selective marker protein and new claim 31 further defines a host cell as supported by the originally filed specification. Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

### **Issues with Respect to the Sequence Listing**

The Examiner has provided a new rejection concerning sequence compliance due to the recitation of certain sequences in claims 22 and 24. However, Applicants traverse and submit that claims 22 and 24 have been canceled. Thus, this rejection is moot. Reconsideration and withdrawal is therefore respectfully requested.

**Issues under 35 U. S. C. § 112, second paragraph**

The Examiner has rejected claims 11, 12, 14-16, 22, 24 and 27-29 under 35 U.S.C. § 112, second paragraph for the reasons recited at pages 4-9 of the outstanding Office Action.

Applicants respectfully traverse this rejection.

First, the Examiner has rejected claim 11 asserting that it is unclear which values of expression amounts are actually being compared and relative that is unclear what Applicant intend by “the value of expression amount measured in the step (ii) and (of said reporter gene).” Applicants traverse and submit that claim 11 has been clarified to indicate that the assessing step relates to assessing the chemical substance to have agonist activity over the transcription promoting ability of the ligand-responsive transcription control factor when the value of expression of said reporter protein as measured in step (ii) is larger than a value of expression amount of said reporter protein as measured in the cell cultured in the absence of chemical substance. Thus, Applicants respectfully submit that claim 11 is fully definite.

Second, the Examiner queries with respect to claim 14 as to whether or not Applicants intend the introduced DNA comprising genes (a) and (b), the introduced ligand-responsive control factor, or both. Applicants traverse and submit that claim 14 has been clarified in this nature.

Third, the Examiner has rejected claim 22 and claim 24 for reasons recited at pages 7-8 of the Office Action. However, these claims have been canceled, thus, this rejection is moot.

In view of the above, Applicants respectfully submit that the present claims define subject matter which satisfies the requirements of 35 U.S.C. § 112, second paragraph. The Examiner is respectfully requested to withdraw these rejections.

**Issues under 35 U.S.C. §112, first paragraph**

The Examiner has rejected claim 19 under 35 U.S.C. §112, first paragraph (written description) for the reasons recited at pages 9-11 of the outstanding Office Action. Applicants respectfully traverse and submit that claim 19 has been canceled. Thus, this rejection is moot.

The Examiner has also rejected claims 1-9, 11-17 and 19-29 under 35 U.S.C. §112, first paragraph (written description) for the reasons recited at pages 11-19 of the outstanding Office Action.

The Examiner further rejects the same claims under 35 U.S.C. §112, first paragraph (enablement) for these reasons recited at pages 19-25 of the outstanding Office Action.

Applicants respectfully traverse each of these rejections.

Applicants respectfully submit that the claims subject to this rejection which remain pending (see claims 1, 4, 6-9 and 11-16) fully satisfy both the written description and the enablement requirements of 35 U.S.C. §112, first paragraph. Applicants point out that the present specification provides detailed information of nucleic acid molecules and cells encompassed by the amended claims. For example, the present specification specifically describes a ligand-responsive transcription control factor selected from an aryl hydrocarbon, receptor, estrogen

receptor, androgen receptor or thyroid hormone receptor, recognition sequences of the ligand-responsive transcription control factors, polynucleotides encoding reporter genes, a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5, polynucleotides encoding selective marker proteins, host animal cells and the like with specific examples. Further discussed is the sequence identified in the sequence listing, methods for obtaining those molecules and cells, and the like. In addition, the amended claims do not include the term "gene" and do not include the limitation "c". Further, the amended claims do not recite the gene (c).

In summary, Applicants submit that those of skill in the art fully understand that Applicants were in possession of the invention as claimed at the time of filing. Moreover, those of skill in the art are fully able to make and use the presently claimed subject matter without undue experimentation. Thus, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

**Issues under 35 U.S.C. § 102(b)**

The Examiner has rejected claims 1-2, 5, 13-14, 17 and 25-28 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,512,483 (hereinafter referred to as the '483 Patent). Applicants respectfully traverse this rejection.

Of the claims originally rejected by the Examiner, only claims 1, 13 and 14 remain pending. Within these claims, there exists a requirement that the ligand-responsive transcription control factor is one selected from an aryl hydrocarbon receptor, an estrogen receptor, an androgen receptor or a thyroid hormone receptor. The claims further require a minimum

promoter comprising the nucleotide sequence of SEQ ID NO: 5. Each of these referenced limitations is absent from the '483 Patent. Thus, there can exist no anticipation. The Examiner is therefore requested to withdraw this rejection.

**Issues under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 1, 3-9, 11 and 14-17 under 35 U.S.C. §103(a) as being obvious over Bradfield et al. (U.S.P. 6,650,283) in view of Waldman (Analytical Biochemistry **258**:216-222, 1998). Applicants respectfully traverse this rejection. Similar to the above, the remaining claims subject to this rejection (claims 1, 4, 6-9, 11 and 14-16) each require a minimum promoter comprising the nucleotide sequence of SEQ ID NO:5. This subject matter is completely absent from the cited art as evidenced by the absence of previously presented claim 23, now canceled, in the Examiner's rejection. As such, Applicants respectfully request that the Examiner withdraw this rejection.

The Examiner has also rejected claims 1-9, 11-12 and 14-17 under 35 U.S.C. § 103(a) as being obvious over Bradfield et al. in view of Waldman and further in view of Kushner et al. (U.S. Patent 6,117,638). Applicants respectfully traverse this rejection. Similar to the above, the present claims require a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5. This subject matter is fully absent from the cited art, thus, there exists no *prima facie* case of obviousness.

The Examiner has also rejected claims 1, 3-9, 11, 14-17, 19, 21 and 25-29 under 35 U.S.C. § 103(a) as being obvious over Bradfield et al., in view of Waldman and further in view

of O'Malley et al. (U.S.P. 5,834,213). Applicants respectfully traverse this rejection and submit that the presently pending claims as require a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5. This subject matter is absent from the cited art, thus, there exists no *prima facie* case of obviousness.

Lastly, the Examiner has newly rejected claims 20, 22 and 25-29 under 35 U.S.C. § 103(a) as being obvious over Mader in view of Carter. Applicants respectfully traverse this rejection and submit that the presently pending claims require a minimum promoter comprising the nucleotide sequence of SEQ ID NO: 5. This specific subject matter is absent from the cited art, thus, there exists no *prima facie* case of obviousness.

In view of the above, Applicants respectfully submit that each of the Examiner's rejections under 35 U.S.C. § 103(a) are moot. The Examiner is therefore respectfully requested to withdraw each of these rejection.

In summary, Applicants submit that the present claims satisfy all statutory requirements for patentability. Accordingly, the Examiner is respectfully to withdraw all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42, 874 at the offices Birch, Stewart, Kolasch & Birch, LLP.


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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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